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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,668	08/28/2003	Alexei Brooun	SYR-ISPA-5001-C1	9129
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TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121				
EXAMINER KIM, ALEXANDER D				
ART UNIT		PAPER NUMBER		

1656

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/651,668

Applicant(s)

BROOUN ET AL.

Examiner

Alexander D. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9,10 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9,10 and 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 07/03/2006
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Application Status***

1. In response to the previous Office actions, a non-Final rejection (mailed on 03/31/2006), Applicants filed a response and amendment received on 07/05/2006. Said amendment cancelled Claims 2-3, 7-8 and 11-15, amended Claims 1, 4-6 and 9, added new claims 16-23. Thus Claims 1, 4-6, 9-10 and 16-23 are pending in the instant Office action.

***Priority***

2. As previously noted, the application claims no priority for benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

***Information Disclosure Statement***

3. The information disclosure statement (IDS) filed on 07/03/2006 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

***Withdrawn-Compliance with Sequence Rules***

4. Previous non-compliance with sequence rules is withdrawn by virtue of Applicants' amendment.

***Withdrawn-Objections to the Specification***

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5. Previous objection of the title is withdrawn by virtue of Applicants' amendment.
6. Previous objection of the specification contains statement "residues 1-299 (from SEQ. ID No.1) is withdrawn by virtue of Applicants' amendment.
7. Previous objection of the specification because of the typographical errors in the specification page 47 §00180 is withdrawn by virtue of Applicants' amendment.
8. Previous objection of the specification citing "amino acid residues 694-753 (SEQ. ID No. 1)" on page 47 §00180 is withdrawn by virtue of Applicants' amendment.
9. Previous objection of the typographical error in the specification page 48 §00180 is withdrawn by virtue of Applicants' amendment.
10. Previous objection of the specification citing "underlined" on page 48 §00180 to indicate the 6x-Histidine tag and rTev cleavage site sequences is withdrawn by virtue of Applicants' amendment.
11. Previous objection of the specification citing "IspA protein samples (corresponding to SEQ. ID No. 1)" that were used in the crystallization (see Example 2, page 49 §00183) is withdrawn by virtue of Applicants' amendment.

***Maintained-Objections to the Specification***

12. Previous objection of the Abstract because of incomplete description of the disclosed subject matter (see M.P.E.P. § 08.01(b)) is maintained. No amendment or argument of the Abstract objection was disclosed in the Argument/Remark filed on 07/05/2006.

***Withdrawn-Claim Rejections - 35 USC § 112***

13. Previous rejection of Claims 4 and 9 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicants' amendment.

***Maintained-Claim Rejections - 35 USC § 112***

14. Previous rejection of Claims 1, 4-6 and 9-10 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that amending claims to include 1-314 of SEQ ID NO: 1 which is shown in Figure 1 satisfies the written description. However, claims do not have adequate description because of lacking "any molecule bound" (see middle of p. 11 in the previous office action) to the instant crystal. The claim 1 does not disclose the space group of the crystal, for example. For the reasons above, the instant rejection is maintained.

15. Previously rejection of claims 6 and 9-10 under 35 U.S.C. 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered

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but are not deemed persuasive for the following reasons. Applicants argue that amending claims to include 1-314 of SEQ ID NO: 1 which is shown in Figure 1 satisfies the written description. However, claims failed to disclose "(2) any ligand added" and "(3) the precipitant solution" (see middle of p. 14 in the previous office action). For the reasons above, the instant rejection is maintained.

16. Previous rejection of claim(s) 1, 4-6 and 9-10 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that amending claims to include 1-314 of SEQ ID NO: 1 which is shown in Figure 1 satisfies the scope of enablement. The crystallization of protein SEQ ID NO: 1 is enabled only in the presence of two ligands with the precipitation condition as described in the specification thus instant application does not disclose adequately for enablement of full scope of claims disclosing any precipitant solution. For the reasons above, the instant rejection is maintained.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

17. Claims 16 and 19 are rejected under 35 U.S.C. § 112, first paragraph, written description, for the same reasons noted in previous office action NO. 11 and herein for the same rejection of Claims 1, 4-6 and 9-10. The composition of claim 19 reads on a crystal comprising a protein of SEQ ID NO. 1.

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18. Claims 17-18 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, written description, for the same reasons noted in previous office action NO. 12 and herein for the same rejection of Claims 6 and 9-10.

19. Claims 16-19 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, for the same reasons noted in previous office action NO. 13 and herein for the same rejection of Claims 1, 4-6 and 9-10. The composition of claim 19 reads on a crystal comprising a protein of SEQ ID NO. 1.

### ***Summary of Pending Issues***

20. The following is a summary of the issues pending in the instant application:

- a. The Abstract stands objected to for not completely describing the disclosed subject matter.
- b. Claims 1, 4-6 and 9-10 stand rejected under 35 U.S.C. § 112, first paragraph, written description for lacking adequate disclosure.
- c. Claims 6 and 9-10 stand rejected under 35 U.S.C. 112, first paragraph, written description for lacking adequate disclosure.
- d. Claim(s) 1, 4-6 and 9-10 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement.
- e. Claims 16 and 19 are rejected under 35 U.S.C. § 112, first paragraph, written description.
- f. Claims 17-18 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, written description.
- g. Claims 16-19 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

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### **Conclusion**

21. Claims 1, 4-6, 9-10 and 16-23 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim  
July 28, 2006

  
KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER